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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DURWARD I. FARIES, JR., BRUCE R. HEYMANN,
CALVIN BLANKENSHIP, and DAVID HENDRIX

Appeal 2009-003410
Application 10/016,128
Technology Center 3700

Before: WILLIAM F. PATE III, STEFAN STAICOVICI, and
KEN B. BARRETT, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 17-23 and 51-62. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

The claims are directed to a method and apparatus for heating solutions within intravenous lines to desired temperatures during infusion. Claim 17, reproduced below, is illustrative of the claimed subject matter:

17. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device, said cassette comprising:

fluid line tubing including an inlet tubing portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet tubing portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet terminals each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid line tubing further includes a spiral portion including a plurality of nested tubing sections in fluid communication with said inlet and outlet tubing portions and arranged adjacent each other to directly transfer heat between said adjacent tubing sections to heat said fluid from said intravenous fluid line, each said tubing section defining a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each tubing section is opposite the fluid flow direction within each tubing section adjacent that section;

wherein the quantity of said tubing sections within said spiral portion is based on providing a residence time for said fluid within said fluid line tubing enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Ikegame	US 4,747,450	May 31, 1988
Mitsunaga	US 6,788,885 B2	Sep. 7, 2004
Augustine	US 2001/009610 A1	Jul. 26, 2001

REJECTIONS

Claims 17, 51, and 57 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Ans. 3.

Claims 17-23 and 51-62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Augustine, Mitsunaga and Ikegame. Ans. 3.

OPINION

The first issue raised by Appellants is whether claims 17, 51, and 57 satisfy the written description requirement. App. Br. 11-12. The Examiner contends that since the original disclosure only described heating the fluid to a desired temperature within the *approximate* range of 60°F to 160°F there is no support for the newly added limitation of heating the fluid to a desired temperature within the range of 60°F to 160°F. The standard for determining compliance with the written description requirement is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citations omitted). The example provided by the Examiner is not relevant to this determination. Ans. 4. If Appellants had possession of a device capable of heating a fluid to a desired temperature

within an approximate range of 60°F to 160°F, which includes temperatures slightly outside the endpoints of that range, one of ordinary skill in the art would understand that the device would also be capable of heating that fluid to a desired temperature within that range since the actual range is a subset of, and therefore narrower than, the approximate range. We must therefore reverse the Examiner's rejection of claims 17, 51, and 57 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

The next issue raised by Appellants is whether the Examiner erred by rejecting claims 17-19, 21, 23, 51-53, 55-59, 61 and 62² as being unpatentable over Augustine, Mitsunaga and Ikegame. App. Br. 14-23. Appellants address each reference individually contending that none of Augustine, Mitsunaga, or Ikegame discloses, teaches or suggests the claim limitation requiring nested or concentric sections with opposing fluid flow directions, wherein the quantity of the nested or concentric sections is based on a fluid residence time to heat fluid to a desired temperature in a range of 60°F to 160°F as recited in the independent claims. App. Br. 14-18; Reply Br. 6. This argument is not relevant to the Examiner's determination of obviousness based upon a *combination* of references. Appellants do not dispute the following factual findings made by the Examiner (Ans. 3-5) and we adopt them as our own:

1. Augustine discloses an intravenous fluid warming device including a fluid filled cassette 104 having tubing surrounded by opposing warming plates 122, 124. P. 2, para. [0027], figs. 1, 2. Augustine discloses that the warming device can heat a fluid to a desired

² As grouped by Appellants. App. Br. 14-23.

temperature, citing a specific example, 98.6°F, within the claimed range. P. 1-2, paras. [0004], [0011].

2. Augustine does not disclose that the length or quantity of tubing used is based upon providing a residence time enabling heating to the desired temperature. Instead, Augustine suggests two methods for controlling the fluid temperature: adjusting the temperature of the warming plates 122, 124 and adjusting the flow rate of the fluid. P. 4, para. [0037].
3. Augustine also does not disclose that the tubing includes a spiral portion. Augustine instead uses a serpentine arrangement. P. 3, para. [0030], fig. 1.
4. Mitsunaga demonstrates that it was known in the art to vary a length of tubing within an intravenous fluid warming device in order to control the residence time of the fluid between the warming plates 202, 204, which enables warming of that fluid to a desired temperature. Col. 6, ll. 38-51.
5. Ikegame demonstrates that it was known in the art that using tubing arranged in a nested spiral pattern 12 in a system wherein heat is transferred from warm elements, such as a semiconductors 2, to a fluid contained in that tubing, has certain advantages over a system using tubing arranged in a zig-zag or serpentine pattern 9. Col. 1, ll. 35-50; col. 3, ll. 20-36. Specifically, reducing thermal stresses on the warm elements 2, minimizing heat loss, and improving the heat transfer to the fluid. Col. 4, ll. 19-30.

Augustine discloses the basic device claimed. *See* Fact 1. Selecting a particular length or quantity of tubing in an intravenous fluid warming

device, as was done by Mitsunaga, would have the predictable result of controlling the residence time of the fluid in between the plates. *See Fact 4.* This would have essentially the same predictable effect on heating the fluid as varying the flow rate, as suggested by Augustine. *See Fact 2.* Thus, modification of Augustine's device such that the quantity of tubing is based upon providing an adequate residence time for the fluid to be heated to a desired temperature amounts to the predictable use of prior-art elements according to their established functions. Such a modification also amounts to the simple substitution of known elements and techniques. For these reasons we find that this modification would have been obvious to one having ordinary skill in the art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416-418 (2007).

Using tubing arranged in a spiral pattern in place of tubing arranged in a serpentine or zig-zag pattern, as was done by Ikegame, would have the predictable result of reducing thermal stresses on the warm element, minimizing heat loss, and improving the heat transfer to the fluid. *See Facts 3 and 5.* Thus, such a modification also amounts to using a known technique to improve a known device in a predictable way. For this reason this modification would have been obvious to one having ordinary skill in the art. *See KSR*, 550 U.S. at 417.

Appellants' remaining arguments regarding independent claims 17, 51 and 57 have been carefully considered but are unpersuasive. For the reasons indicated above and those articulated in the Answer, we find that Appellants' argument that there would have been no apparent reason to combine the teachings of Augustine, Mitsunaga and Ikegame is unpersuasive. *See App. Br. 19-20; Ans. 3-5.*

Appellants' argument concerning the compatibility of Mitsunaga's cartridge with Augustine's warming unit (App. Br. 20-21; Reply Br. 8) is also unpersuasive because "it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (citations omitted). Such a modification to Augustine's device essentially involves only an alteration of the size and/or shape of Augustine's warming unit so that the heating structures correspond to the cassette structure. Thus, one of ordinary skill in the art would have known how to incorporate the teachings of Mitsunaga into the device of Augustine in order to arrive at a working device. The fact that Augustine does not mention the heating technique of Mitsunaga does not amount to "specifically exclud[ing]" it as Appellants suggest. *Contra* Reply Br. 7.

Appellants contend that Ikegame teaches away from the claimed invention but Appellants do not point to anything in Ikegame which criticizes, discredits, or otherwise discourages the solution claimed. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). The fact that Ikegame is concerned with the end temperature of the warming element, the semiconductor, as opposed to the fluid used for cooling it, does not lead to the conclusion that one of ordinary skill in the art would not regard Ikegame's teachings regarding the advantages of a spiral design over a serpentine one as relevant to Augustine's device. *Contra* App. Br. 21-22; Reply Br. 9-10. Both structures are concerned with the heat transfer from warm elements to a fluid passing therebetween. In either case, reducing the thermal stresses on the warming elements, whether they are semiconductors or heating plates, would provide the advantageous result of improving the life expectancy of the device. Whether the final goal is attaining a specific

temperature of the warming elements, or a specific temperature of the fluid passing therebetween, in either case, minimizing heat loss and improving the heat transfer to the fluid would have the advantageous result of improving efficiency and enabling a reduction in the overall size of the device. Again it is the teachings of Ikegame, and not the specific structure, that must be considered in an obviousness analysis. We agree with the Examiner that one of ordinary skill in the art would have recognized Ikegame's teachings as relevant to those of Augustine and Mitsunaga. Ans. 6.

For these reasons, the rejection of claims 17-19, 21, 23, 51-53, 55-59, 61 and 62 is affirmed.

Regarding dependent claims 20, 54, and 60, we agree with Appellants that the Examiner erred by finding that Augustine discloses a detectable conductive contact disposed about a portion of said fluid line tubing. We recognize that Augustine suggests a structure 126/128/129/153 for performing the recited function of indicating the presence of the cassette within the warming device. P. 2-3, paras. [0028] – [0030]. However, Augustine does not disclose the structure as claimed because there is no conductive contact disposed about or surrounding a portion of the tubing. App. Br. 24-25; Reply Br. 10-11; *see, e.g.*, Augustine Fig. 8. There is no legally recognizable essential gist or heart of the invention. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983) (citations omitted). All words in a claim must be considered in judging the obviousness of the claimed subject matter. *See In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). Thus, the rejection of claims 20, 54 and 60 must be reversed.

Regarding dependent claim 22, we agree with Appellants that since the Examiner has not mentioned the specific features of this claim and since

it is not apparent from the reference, the Examiner failed to articulate a reason why the claimed subject matter would have been obvious. *KSR*, 550 U.S. at 418. We recognize that *Augustine* does suggest a sensor for performing the recited function of measuring the temperature of the fluid flowing within the device and that sensor may be in the fluid pathway 144. P. 3, para. [0030]. However, *Augustine* does not disclose a conductive member disposed within a fitting in the fluid pathway receiving a temperature sensor as required by claim 22. App. Br. 26; Reply Br. 12. Again, all words in a claim must be considered in judging the obviousness of the claimed subject matter. Thus, the rejection of claim 22 must be reversed.

DECISION

The Examiner's rejection of claims 17, 51, and 57 under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement is reversed.

The Examiner's rejection of claims 17-19, 21, 23, 51-53, 55-59, 61 and 62 under 35 U.S.C. § 103(a) as being unpatentable over *Augustine*, *Mitsunaga* and *Ikegame* is affirmed.

The Examiner's rejection of claims 20, 22, 54, and 60 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART

Appeal 2009-003410
Application 10/016,128

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